REMARKS/ARGUMENTS

Applicant respectfully requests reconsideration of the above-identified application. A consultant to the assignee recently completed a prior art search regarding fluid evacuation. The results are listed in the enclosed Information Disclosure Statement.

With the present amendment, claim 16 has been amended to include the language "said transfer channel being in heat transfer isolation from said cannula assembly outer surface". Claims 18, 37, 39, and 41 have been cancelled. Claim 44 has been amended to include the language "said transfer channel being in thermal isolation from said cannula assembly outer surface". Claims 45, 64, 66, and 68 have been cancelled. Included herewith is a Declaration under 37 C.F.R. 1.132 from the inventor, Philip E. Eggers, the specific paragraphs of which are referred to throughout the remainder of this response as "Declaration, ¶ __".

In anticipation of allowance of a generic claim, dependent, non-elected species claims 56-60 and 62 have been amended to correct an obvious typographical error. Each claim's preamble originally recited "apparatus" instead of the proper "system" set forth in independent claim 44. Appropriate correction has been made.

Claims 16-21, 40, 42-48 and 54 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,814,044 issued September 29, 1998 to Hooven (hereinafter, "Hooven").

The present invention is addressed to method, system and apparatus for carrying out interstitially located electrosurgical cutting while avoiding collateral thermal trauma to healthy tissue, as well as thermal damage to any target tissue specimen sought to be retrieved for biopsy.

As tissue is severed by application of an interstitially positioned electrosurgical cutting arc, elevated temperature fluids including steam, any heated gases and liquids including blood and anesthetic solution, are contemporaneously removed through an intake port located in the vicinity of tissue severance. These hot fluids are directed along a transfer channel for external disposition. As the elevated temperature fluids traverse the cannula component of an involved electrosurgical instrument, external surfaces of that instrument itself may be heated to tissue damaging temperatures. Such damage is avoided under the precepts of the instant invention by a variety of thermal insulation approaches, the selection of which may be predicated upon the ultimately developed physical size extent of the cutting electrode utilized and an attendant duration of the cutting procedure.

One such thermal insulation approach, for example, employs a cannula component internally incorporating a heated fluid transfer channel that is externally insulated by a thermal

barrier configured as a thermal insulator sheath. That sheath may be provided as a tube having an inner wall surface spaced from the exterior surface of the cannula component. In another embodiment the insulator sheath is formed as an extruded polymeric tube having an array of internally depending rib-form standoffs aligned in parallel with the axis of the cannular instrument.

In studies of the surface heating characteristics of cannulas with and without shielding, Applicant demonstrated the importance of thermal shielding. Results of Applicant's conducted studies are set forth in the application at page 23, line 33 through page 27, line 24 and associated Figs. 21-25. As one example, Applicant determined in an in vitro study that, without thermal shielding, the surface temperature of the cannula component may exceed 90° Celsius when a large tissue sample is collected. By comparison, the surface temperature when thermal shielding is employed will be only slightly greater than 50° Celsius, and the temperature of the thermal shield against the tissue will remain close to 40° Celsius.

As described in the annexed declaration of Philip E. Eggers and in the patent itself, Hoover is addressed to apparatus and method for morselating and removing tissue. Hoover's device is a morselator comprising "an elongated shaft having an inner tube and an outer tube extending between proximal and distal end portions. At least one of the tubes is rotatable and an electrode surface is carried by the rotatable tube(s) in proximity to the distal end thereof." Hoover, Col. 2, lines 37-41. In use, the distal end of the device is inserted through an incision in the patient and the electrode energized, rotated and advanced into the resected tissue in order to morselate it. Hoover, Col. 2, lines 42-47. In Hoover, the term "morselating means cutting, coring, slicing, chopping, or any other way of subdividing tissue into smaller pieces." Hoover, Col. 4, lines 55-58. The morselated tissue then is removed, such as by suction through the shaft. Hoover, Col. 2, lines 46-47 and Col. 7, lines 12-31. Nowhere does Hoover identify let alone address the problem of heat generated from an interstitial electrosurgical cutting procedure, which causes damage to healthy tissue surrounding the instrument. Declaration, ¶ 11.

Independent claim 16 recites an apparatus comprising a cannula assembly having a forward region and an electrosurgical cutting assembly mounted at the forward region of the cannula and which supports a cutting arc effecting the generation of elevated temperature fluid when electrosurgically energized. The apparatus also includes an intake port at the cannula forward region for collecting at least a portion of the elevated temperature fluid. A transfer channel is provided in fluid transfer relationship with the intake port and through which the

elevated temperature fluid is expressible. As amended, claim 16 recites that the transfer channel is in heat transfer isolation from the cannula assembly's outer surface.

Hoover does not disclose thermally insulating the transfer channel from the cannula assembly outer surface. This is not surprising because, as noted above, Hoover neither discloses nor teaches the problem of elevated temperature fluids generated during an electrosurgical procedure. Drawing tissue through a transfer channel will not cause damage to healthy tissue surrounding or proximate to the device. Such is not the case when withdrawing elevated temperature fluid through the transfer channel where elevated temperature fluid will raise the temperature of the cannula's outer surface resulting in collateral thermal damage.

Thermal damage also is not an issue for Hooven because with the exception of the distal end, the outer tube of Hooven's instrument does not contact patient tissue. Hooven's instrument is used laparoscopically, the surgeon inserting a trocar assembly having a hollow sleeve through the patient's abdominal wall and thereafter inserting Hooven's instrument through the sleeve to access the site where surgeon performs the morselating procedure. Declaration, ¶ 12. Thus, the outer tube of Hooven's instrument is not directly in contact with patient tissue as is the case for the present invention which is used in an interstitial surgical cutting procedure.

The Examiner states that, "The inner and outer tubes may be made from a variety of materials, including thermally insulative plastics or metals coated with insulative plastics (see column 5, line 40 through column 6, line 30)." The term "thermally insulative" is not used anywhere in Hooven. The only term used is "insulating" and a full reading of the patent reveals that the term "insulating" means electrically insulating and not thermally insulating. Declaration, ¶ 13. Looking to the language cited by the Examiner, Hooven says that, "The inner and outer tubes are preferably made of a substantially electrically non-conductive material, such as a fiber glass-epoxy composite or a polymer. Alternatively, the walls of the inner and outer tubes may have a metal core for strength and be coated with a substantially non-conductive or insulating material." At Col. 6, lines 9-10, Hooven specifically states that, "'Insulating' and 'non-conducting' are used interchangeably in this description." There simply is no teaching or suggestion that the inner and outer tube materials disclosed in Hooven would be able to withstand the heat produced by the elevated temperature fluids generated during an interstitial electrosurgical cutting procedure. Declartation, ¶ 15. The material that is disclosed, namely, fiberglass epoxy having a thickness of approximately 0.007 inches, would be an insufficient thermal barrier to prevent iatrogenic injury at the noted elevated temperatures. Declaration, ¶ 14.

The Examiner also cites Hooven as having an air gap between an outer cannula and an evacuation channel, the air gap inherently acting as a heat transfer isolation mechanism. There is no teaching or suggestion that the air gap shown in Hooven, for example in Fig. 6b, would be sufficient for the outer tube to be in heat transfer isolation from the inner tube for an interstitial procedure evoking such elevated temperature fluids. Declaration, ¶ 16.

As set forth in the Manual of Patent Examining Procedure § 2112, "The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." (emphasis in original). That section goes to state that, "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.... In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." (emphasis in original).

In view of the above, it is clear Hooven does not disclose or suggest "a transfer channel in fluid transfer relationship with said intake port and extending therefrom along said cannula assembly to an evacuation outlet through which said elevated temperature fluid is expressible, said transfer channel being in heat transfer isolation from said cannula assembly outer surface" as required by claim 16. Declaration, ¶ 17.

Claim 17, which depends from claim 16, should be considered patentable for the reasons given above.

As noted above, claim 18 has been cancelled.

Claims 19-21 recite further features of the heat transfer isolation of the transfer channel from the cannula assembly outer surface. Claim 19, dependent on claim 17, recites that "said cannula assembly comprises a cannula component configured as a tube formed of thermally insulative material." As noted above, Hooven does not teach or disclose the use of thermally insulative material. Claim 20, also dependent on claim 17, recites "a thermally insulative sheath extending over said cannula component outwardly disposed component surface." Sucha sheath is not disclosed in Hooven. Claim 21, which depends from claim 20, additionally recites that "said thermally insulative sheath is formed of thermally insulative material." As noted above, heat isolation of the transfer channel by any means is neither disclosed nor suggested by Hooven.

Claim 40, depending from independent claim 16, should be considered patentable for the reasons given in connection with claim 16. Claim 42 further recites "at least one electrosurgically energizable precursor electrode positioned at said tip, said precursor electrode supporting a cutting arc effecting the generation of positioning elevated temperature fluid." A precursor electrode is neither disclosed nor suggested in Hooven. Claim 43 depending from independent claim 16, should be considered patentable for the reasons given in connection with claim 16.

Independent claim 44 recites a system comprising the above noted-apparatus in combination with an electrosurgical generator, a suction source, and an evacuation conduit. Claim 44 has been amended to recite that the transfer channel of the apparatus is in thermal isolation from the cannula assembly outer surface. Claim 44, and claims 45-48 and 54, which depend from claim 44, should be considered patentable for the reasons given in connection with claim 16.

Applicant notes with appreciation that the Examiner has indicated claims 22, 28, 49, 53, and 55 to be allowable. In view of the foregoing, wherein the claim program as amended has been shown to readily distinguish over the references of record, issuance of a Notice of Allowance earnestly is solicited for all elected claims 16-69.

Respectfully submitted,

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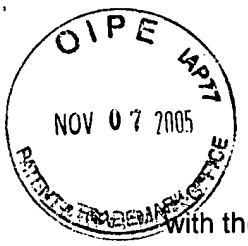

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